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| APPLICATION NO.         | FILING DATE    | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|----------------|-------------------------|---------------------|------------------|
| 09/870,113              | 05/30/2001     | C. Alexander Turner JR. | LEX-0182-USA        | 6538             |
| 7                       | 590 02/19/2003 |                         |                     |                  |
| Lance K. Ishimoto       |                |                         | EXAMINER            |                  |
| 4000 Research           |                |                         | RAO, MANJUNATH N    |                  |
| The Woodlands, TX 77381 |                |                         | ART UNIT            | PAPER NUMBER     |
|                         |                |                         | 1652                |                  |
|                         |                | DATE MAILED: 02/19/2003 |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| . •   |  | Application No.                    | Applicant(s)                  |  |  |  |
|---|--|------------------------------------|-------------------------------|--|--|--|
| Office Action Summary   |  | 09/870,113                         | TURNER ET AL.                 |  |  |  |
|   |  | Examiner                           | Art Unit                      |  |  |  |
|   | •  | Manjunath N. Rao, Ph.D.            | 1652                          |  |  |  |
|   | The MAILING DATE of this communication app   | ears on the cover sheet with the c | orrespondence address         |  |  |  |
| P riod fo   | • •  | LIG OFT TO EVEIDE AMONTHU          | 0) 50014                      |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                    |                               |  |  |  |
| Status  | 5 (Co. 45) 51 and an 44 A  | 40000                              |                               |  |  |  |
| 1)🖂   | Responsive to communication(s) filed on 14 A                                       |                                    |                               |  |  |  |
| 2a)☐  | ,  | is action is non-final.            | acception as to the marite is |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |                                    |                               |  |  |  |
| Disposition of Claims   |  |                                    |                               |  |  |  |
| 4) Claim(s) 1-3 is/are pending in the application.  |  |                                    |                               |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |                                    |                               |  |  |  |
|   | 5) Claim(s) is/are allowed.  |                                    |                               |  |  |  |
|   | 6)⊠ Claim(s) <u>1-3</u> is/are rejected.   |                                    |                               |  |  |  |
| •   | Claim(s) is/are objected to.   |                                    | •                             |  |  |  |
| , —   | Claim(s) are subject to restriction and/or on Papers                               | r election requirement.            |                               |  |  |  |
|   | The specification is objected to by the Examine                                    | r                                  |                               |  |  |  |
| • —   | The drawing(s) filed on is/are: a)☐ accep  |                                    | miner                         |  |  |  |
| الساراة   | Applicant may not request that any objection to the                                |                                    |                               |  |  |  |
| 11)[ 7  | The proposed drawing correction filed on   |                                    |                               |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |                                    |                               |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |  |                                    |                               |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |                                    |                               |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |                                    |                               |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |                                    |                               |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |                                    |                               |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No |                                    |                               |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                                    |                               |  |  |  |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |  |                                    |                               |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |  |                                    |                               |  |  |  |
| Attachment(s)   |  |                                    |                               |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   |  |                                    |                               |  |  |  |

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### **DETAILED ACTION**

Claims 1-3 are currently pending in this application.

### Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "drawn from the group". It is not clear to the Examiner as to what applicants mean by the above phrase. Examiner suggests amending the claim to recite "selected from the group" as opposed to the use of the above phrase.

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The applicant has not asserted at least one utility for the claimed isolated polynucleotides encoding the amino acid sequences with of SEQ ID NO:2, 4, 6, 8, 10 and 12.

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Applicant has characterized the polynucleotides as those that encode novel human mitochondrial proteins which share structural motifs typical of mitochondrial solute carriers, RNA splicing proteins, uncoupling proteins and mitochondrial carrier proteins. However, applicants do not first of all do not provide the information as to which specific polypeptide has which specific function. Applicants have simply provide a group of polypeptides and broadly assigned the functional characteristics to the group of the polypeptides and are now claiming the polynucleotides which encode them. Second applicants do not denote as to which specific solute is carried by which specific protein (i.e., which specific SEQ ID NO) in the case of mitochondrial solute carriers or as to which specific RNA is spliced in the case of RNA splicing proteins. Thus the functional characteristics or the ultimate utility of the polypeptides encoded bythe claimed polynucleotides is not specific and substantiated. Therefore, other than the polynucleotide sequence, SEQ ID NO:1, 3, 5, 7, 9, 11 and the amino sequence that is encoded by the polynucleotide as set forth in SEQ ID NO:2, 4, 6, 8, 10 and 12 respectively, the specification provides little functional characterization of the claimed polynucleotides. The specification also lists a general use for the polypeptides encoded by the polynucleotides, however, there is no information that links the use of the polynucleotides with SEQ ID NO: 1, 3, 5, 7, 9, 11. Thus the asserted utility of the claimed polynucleotides is not substantial or specific. Further, while the specification discloses that SEQ ID NO: 1, 3, 5, 7, 9, 11 and its fragments will be used to generate probes, and the encoded polypeptides will be used for making antibodies, that is not a utility specific to the claimed polynucleotide or polypeptide sequence.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of U.S.C. 101, published in the Official Gazette and also available at <a href="https://www.uspto.gov">www.uspto.gov</a>.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NO:1, 3, 5, 7, 9 or 11 or DNA encoding a polypeptide with SEQ ID NO:2, 4, 6, 8, 10 and 12.

The specification does not contain any disclosure of the function of all DNA sequences SEQ ID NO: 1, 3, 5, 7, 9 or 11. The genus of DNAs that comprise these above DNA molecules is a variable genus with the potentiality of encoding proteins whose functions are not clearly known. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only the structure of the polynucleotides which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at <a href="https://www.uspto.gov">www.uspto.gov</a>.

#### Conclusion

None of the claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao February 14, 2003